(സി&ഡി) അമേരിക്കയിലെ മയോ ക്ലിനിക്കിന്റെ സഹകരണത്തോടെ ഒരു പ്രമേഹരോഗ ഗവേഷണ വിദ്യാഭ്യാസ പരിശീലനകേന്ദ്രം കേരളത്തിൽ സ്ഥാപിക്കുന്നതിനുള്ള നിർദ്ദേശം സർക്കാർ അംഗീകരിക്കുകയും തുടർന്ന് മയോ ക്ലിനിക്കും കേരള സർക്കാരും ഒരു പ്രാഥമികധാരണാപത്രം ഒപ്പുവയ്ക്കുകയും ചെയ്തു. തുടർന്ന് തിരു-കൊച്ചി ചാരിറ്റബിൾ സൊസൈറ്റിസ് രജിസ്ട്രേഷൻ ആക്ട് അനുസരിച്ച് 'ഇൻഡ്യൻ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് ഡയബറ്റീസ് എന്ന സൊസൈറ്റി രജിസ്റ്റർ ചെയ്യുകയുംചെയ്തിട്ടുണ്ട്. ഇതിന്റെ പ്രാരംഭ പ്രവർത്തനങ്ങൾക്കായി ഒരു സ്പെഷ്യൽ ഓഫീസറെ നിയമിച്ചുകഴിഞ്ഞു. തിരുവനന്തപുരത്ത് പുലയനാർകോട്ട ടി.ബി. സാനിട്ടോറിയം വളപ്പിൽ പ്രസ്തുത കേന്ദ്രം സ്ഥാപിക്കുന്നതിനുള്ള നടപടികൾ സ്വീകരിച്ചുവരുന്നു.

(ഇ) വിദേശസഹായം ലഭ്യമാക്കുന്നതിനുള്ള പ്രാരംഭ നടപടികൾ സ്വീകരിച്ചുവരുന്നു.

(എഫ്) ഗവേഷണ കേന്ദ്രത്തിൽ രോഗികളെ കിടത്തി ചികിൽസിക്കുവാൻ ഉദ്ദേശിക്കുന്നുണ്ട്. എണ്ണം കൃത്യമായി നിശ്ചയിച്ചിട്ടില്ല.

(ജി) കേരള സർക്കാരിനും മയോ ക്ളിനിക്കിനും പ്രാതിനിധ്യമുള്ള സ്വയം ഭരണാവകാശമുള്ള ഗവേണിംഗ് ബോഡിയുടെ നിയന്ത്രണത്തിലായിരിക്കും പ്രസ്തുത കേന്ദ്രം.

(എച്ച്) പ്രസ്തുത കേന്ദ്രം ആരംഭിക്കുന്നതിനുള്ള പ്രാരംഭ നടപടികൾ നടന്നുവരുന്നു. സ്ഥലം അക്വയർ ചെയ്ത്, നിർമ്മാണ പ്രവർത്തനങ്ങൾ പൂർത്തിയാക്കി സൗകര്യങ്ങൾ ലഭ്യമാക്കിയാലുടൻ പ്രവർത്തനം ആരംഭിക്കുവാനാണ് ഉദ്ദേശിക്കുന്നത്.

സമഗ്ര ആരോഗ്യ ഗ്രാമങ്ങൾ ആരംഭിക്കുന്നതിന് നടപടി

11(*296) ശ്രീ. കെ. എം. മാണി :
ശ്രീ. മാമ്മൻ മത്തായി :
ശ്രീ. സി. എഫ്. തോമസ് :
ശ്രീ. കെ. നാരായണക്കുറുപ്പ് : താഴെ കാണുന്ന ചോദ്യങ്ങൾക്ക് ആരോഗ്യവും സ്പോർട്സും വകുപ്പുമന്ത്രി സദയം മറുപടി നൽകുമോ :

(എ) സംസ്ഥാനത്ത് സമഗ്ര ആരോഗ്യഗ്രാമങ്ങൾ ആരംഭിക്കുന്നതിന് പരിപാടിയുണ്ടോ ;

(ബി) എങ്കിൽ വിശദാംശങ്ങൾ വെളിപ്പെടുത്തുമോ ;

(സി) സംസ്ഥാനത്ത് ആയുർവേദ ഔഷധനിർമ്മിതിക്ക് ജി. എം.പി. സർട്ടിഫിക്കറ്റ് ലഭിച്ചിരിക്കണമെന്ന് നിർദ്ദേശിച്ചിട്ടുണ്ടോ ;

(ഡി) ഉണ്ടെങ്കിൽ വിശദാംശങ്ങൾ വ്യക്തമാക്കുമോ ;

(ഇ) സംസ്ഥാനത്ത് കുട്ടികളിൽ മാനസികവൈകല്യങ്ങളും നാഡീരോഗങ്ങളും വർദ്ധിച്ചുവരുന്നുണ്ടെന്ന വാർത്ത ശ്രദ്ധയിൽപ്പെട്ടിട്ടുണ്ടോ ;

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(എഫ്) എങ്കിൽ ഇത് തടയുന്നതിന് എന്തെല്ലാം നടപടികളാണ് സ്വീകരിച്ചുവരുന്നതെന്ന് വിശദീകരിക്കാമോ ?

ആരോഗ്യവും സ്പോർട്സും വകുപ്പുമന്ത്രി (ശ്രീ. വി. സി. കബീർ) :

(എ&ബി) സംസ്ഥാനത്ത് സമഗ്ര ആരോഗ്യഗ്രാമങ്ങൾ ആരംഭിക്കുന്നതിന് പരിപാടിയില്ല.

(സി) സർട്ടിഫിക്കറ്റ് ലഭിച്ചിരിക്കണമെന്ന വ്യവസ്ഥ ഇല്ല എന്നാൽ, ജി.എം.പി. എന്ന പേരിൽ അറിയപ്പെടുന്ന നിയമവ്യവസ്ഥകൾ പാലിക്കേണ്ടതുണ്ട്.

(ഡി) ആയുർവേദ, സിദ്ധ, യുനാനി ഔഷധങ്ങളുടെ ഗുണനിലവാരം ഉറപ്പുവരുത്തുന്നതിനായി 1945-ലെ ഡ്രഗ്സ് ആന്റ് കോസ്മറ്റിക്സ് ചട്ടങ്ങളിൽ ജി. എം. പി. (ഗുഡ് മാനുഫാക്ചറിംഗ് പ്രാക്റ്റീസ്) എന്ന പേരിൽ അറിയപ്പെടുന്ന വ്യവസ്ഥകൾ കേന്ദ്രസർക്കാർ നിർദ്ദേശിച്ചിട്ടുണ്ട്. 23-6-2000 മുതൽ ഇതിന് പ്രാബല്യമുണ്ട്. എന്നാൽ നിലവിലുള്ള നിർമ്മാതാക്കൾക്ക് ഈ വ്യവസ്ഥകൾ പാലിക്കുന്നതിനായി രണ്ടുവർഷത്തെ സമയം അനുവദിച്ചിട്ടുണ്ട്. കേന്ദ്രസർക്കാരിന്റെ ഗസറ്റ് വിജ്ഞാപനത്തിന്റെ പകർപ്പ് അനുബന്ധമായി ചേർക്കുന്നു.†

(ഇ) ഉണ്ട്.

(എഫ്) പ്രസ്തുത രോഗചികിൽസയ്ക്കായി തിരുവനന്തപുരം എസ്.എ.റ്റി ആശുപത്രിയിൽ പീഡിയാട്രിക് ന്യൂറോളജിവിഭാഗം പ്രവർത്തിക്കുന്നു. ഇതു കൂടാതെ ഐ.എസ്.എം. വകുപ്പിന്റെ കീഴിൽ മലപ്പുറം ജില്ലയിലെ കോട്ടയ്ക്കലിൽ ആയുർവേദ മാനസികരോഗാശുപത്രിയും പ്രവർത്തിച്ചുവരുന്നു.

ഉപേക്ഷിക്കപ്പെട്ട മാനസിക രോഗികൾക്ക് പെൻഷൻ പദ്ധതി

12(*297) പ്രൊഫ. മീനാക്ഷി തമ്പാൻ :
ശ്രീ. കെ. പി. രാജേന്ദ്രൻ :
ശ്രീമതി ആർ. ലതാദേവി :
ശ്രീ. എം. നാരായണൻ (ഹോസ്ദുർഗ്) :
ശ്രീ. പി. നാരായണൻ : താഴെ കാണുന്ന ചോദ്യങ്ങൾക്ക് ആരോഗ്യവും സ്പോർട്സും വകുപ്പുമന്ത്രി സദയം മറുപടി നൽകുമോ :

(എ) ബന്ധുക്കളാൽ ഉപേക്ഷിക്കപ്പെട്ട് മാനസികാരോഗ്യ കേന്ദ്രങ്ങളിൽ കഴിയുന്ന മാനസിക രോഗികൾക്ക് പെൻഷൻ പദ്ധതി നടപ്പാക്കാൻ ഉദ്ദേശിക്കുന്നുണ്ടോ ;

(ബി) എങ്കിൽ ഈ പദ്ധതിയുടെ വിശദവിവരങ്ങളും ഈ പദ്ധതി എന്ന് മുതൽ നടപ്പാക്കാനാണ് ഉദ്ദേശിക്കുന്നതെന്നും വെളിപ്പെടുത്തുമോ ?

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† അനുബന്ധം I

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അനുബന്ധം - I

[8-03-2001-ലെ നക്ഷത്രചിഹ്നമിട്ട ചോദ്യം നമ്പർ 11(*296) ദയവായി കാണുക]

भाग II -खण्ड - 3 (i) भारत का रीजपत्र : असाधारण

14.	प्रत्येक विनिर्माण एकक में, भटटी, ब्वौयलर, पुट इत्यादि के लिए पृघक क्षेत्र होगा। इसमें समुचित संवातन, धुंआ निराकरण, मज्छर-भक्खी, किडों, धूल ईत्यादि का निवारण होगा।	२०० वर्ग फुट

टिप्पणो

मशीनरी, उपस्वार, स्थान, अहंताओं की उपरोक्त अपेक्षाएं अनुज्ञापन प्रधिकारी के विवेंक पर उपांरणों के अतीत रहते हुए बनाई गई है: यदि उसकी गय में किसी विशिष्ट मामले की परिस्थितियों में विभिर्माण सक्रियाओं की प्रकृति ओर विस्तार को ध्यान में रखते हूए उन्हें शिथिल या परिवर्तित करना आवश्यक है।

सं.के 11020/5/97-डि. सी. सी. (आई. एस. एस)

एल. प्रसाद, संयुक्त संचिव

पाद- टिप्पणो

मुल नियम राजपत्र में अधिसूचना सं. एक. 28-10/45 एव 1 तारीख 21-12-1995 द्वारा प्रकाशित किए ओर इनमें अंतिम संशोधन सा का नि 352 (अ) ता. 26-4-2000 द्वारा किया गया। 1-5-1979 तक यथा संशोधित औषधि और प्रसाधन सामग्री नियम, 1995, स्वास्थ्य और परिवार कल्याण मंत्रालय स्वास्थ्य विमाग के प्रकारान में अंतर्विष्ट है, जिसमें औषधि और प्रसाधन सामग्री अधिनियम 1940 भी सम्मिलित है।

1.1 (D) Disposal of Waste :

From the manufacturing sections and laboraties the waste water & the residues which might be prejudicial to the workers or public health shall be disposed off after suitable treatment as per guidelines of polution control authorities to render them harmless.

1.1 (E) Container's Cleaning ;

In factories where operations involving the use of containers such as bottles, vials and jars are conducted, there shall be adequate arrangements separated from the manufacturing operations for washing, cleaning and drying of such containers.

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1.1 (F) Stores :

Storage should have proper ventilation and shall be free from dampness. It should provide independent adequate space for storage of different types of materials , such as raw material, packaging material & finished products.

1.1 (F) (A) Raw Materials :

All raw materials procured for manufacturing will be stored in the raw materials store. The manufacture based on the experience and the characteristics of the particular raw material used in Ayurveda, Siddha and Unani system shall decide the use of appropriate containers which would protect.

Quality of the raw material as well as prevent it from damage due to dampness, microbiological contamination or rodent and insect infestation, etc. If certain raw materials require such controlled environmental conditions, the raw materials stores may be sub-divided with proper enclosures to provide such conditions by suitable cabinization. While designing such containers, cabins or areas in the raw materials store, care may be taken to handle the following different categories of raw material:—

(b) in rule 157, after condition(1), the following shall be inserted, namely:—

"(1A) For getting a certificate of 'Good Manufacturing Practices of Ayurveda-Siddha-Unani drugs, the applicant shall make an application on a plain paper, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per Schedule 'T', issue the certificate within a period of 3 months in Form 26E-I"

(c) after Form E, the following form shall be inserted , namely:—

Form 26 E-I
(See rule 157-B)

(Certificate of Good manufacturing Practices (GMP) to manufacturer of Ayurveda, Siddha or Unani drugs) :

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Certified that manufacturing unit licensee, namely....., situated at .....State.....Licence No.....comply with the requirements of Good Manufacturing Practices of Ayurveda-Siddha-Unani drugs as laid down in Schedule T of the Drugs and Cosmetic Rules, 1945.

This Certificate is valid for a period of two years.

Dated: Signature

Place: Designation/

Licensing Authority(ISM&H)

(d) for Schedule 'T', the following shall be substitued, namely:—

SCHEDULE "T"

(See rule 157)

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICIENS

The Good Manufacturing Practices are prescribed to ensure that:

(i) Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination.

(ii) The manufacturing process is as has been prescribed to maintain the standards.

(iii) Adequate quality control measures are adopted and

(iv) The manufactured drug which is released for sale is of acceptable quality.

(v) To achieve the objectives listed above, each licencee shall evolve methodology and procedures for following the prescribed process of manufacture of durgs which should be documented as a manual and kept for reference and inspection. However, teaching in stitutions and registered qualified Vaidyas, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of G.M.P.

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PART I

GOOD MANUFACTURING PRACTICES

Factory Premises :

The manufacturing plant should have adequate space for:—

(i) Receiving and storing raw material.

(ii) Manufacturing process Areas.

(iii) Quality control section.

(iv) Finised goods store

(v) Office

(vi) Rejected goods/drugs store

1.2 General Requirements :

1.1 (A) Location and surroundings :

The factory buildings for manufacture of Ayurveda, Siddha and Unani medicines shall be so situated and shall have such construction as to avoid contamination from open sewrage, drain, public lavatory or any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust or smoke.

1.1 (B) Buildings :

The building used for factory shall be such as to permit production of drugs under hygenic conditions and should be free from cobwebs and insects/rodents. It should have adequate provision of light and ventilation. The floor and the walls should not be damp or moist. The premises used for manufacturing, processing, packaging and labeling will be in conformity with the provisions of the Factory Act. It shall be located so as to be:

I Compatible with other manufacturing operations that may be carried out in the same of adjacent premises.

II Adequately provided with working space to allow orderly and logical placement of equipment and materials to avoid the risk of mix up between different drugs or components thereof and control the possibility of cross contamination by other drugs or substances and

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avoid the risk of omission of any manufacturing or control step:

III Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceillings) shall be smooth and free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean. The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products.

IV Provided with proper drainage system in the processing area. The sanitary fitting and electrical fixtures in the manufacturing area shall be proper and safe.

V Furnance/Bhatti section could be covered with tin roof & proper ventilation, but sufficient care should be taken to prevent flies and dust.

VI There shuold be fire safety measures and proper exits should be there.

1.1 (C) Water Supply :

The water used in manufacture shall be pure and of potable quality. Adequate provision of water for washing the premises shall be made.

NOTIFICATION

New Delhi, the 23rd June, 2000

G.S.R. 561(E).— Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India Extraordinary Part-II, Section 3, Sub-section (i) dated the 24th May, 1999, vide No. GSR 384(E) inviting objections and suggestions from persons likely to be affected thereby and notice was given that the said draft will be taken into consideration after the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the notification were made available to the public ;

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And whereas the said Gazette was made available to the public on 14th May, 1999 ;

And whereas objections and suggestions from the public on the said draft have been considered by the Central Government ;

Now, therefore, in exercise of the powers conferred by section 33-N of the said Act, the Central Government, after consultation with the Ayurveda, Siddha and Unani Drugs Technical Advisory Board hereby makes, the following further amendments in the Drugs and Cosmetics Rules, 1945, namely:—

RULES

1. These rules may be called the Drugs and Cosmetics, (Amendment) Rules, 2000.

   They shall come in to force on the date of their publication in the Official Gazette:

   Provided that in the case of Ayurveda, Siddha and Unani units which have been registered before the date of commencement, these rules shall come in to force after two years from the date of such commencement.

2. In the Drugs & Cosmetics Rule, 1940,

   (a) after rule 155-A, the following rule shall be inserted namely:—

   "155-B Certificate of award of G.M.P. of Ayurveda, Siddha and Unani Drugs: The certificate of Good Manufacturing Practices to manufacturers of Ayurveda-Siddha or Unani drugs shall be issued to licensee who comply with the requirements of Good Manufacturing Practice of Ayurveda, Siddha and Unani drugs as laid down in Schedule T".

   1. Raw material of metallic origin.
   2. Raw material of mineral origin.
   3. Raw material from animal source.
   4. Fresh Herbs.
   5. Dry Herbs or plant parts.

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6. Excipients etc.

7 Volatile oils/perfumes & flavours.

8. Plant extracts and excudates/resins.

Each container used for raw material storage shall be properly identified with the label which indicates name of the material, source of supply and will also clearly state the status of raw material such as 'UNDER TEST' or 'APPROVED' of 'REJECTED'. The labels shall further indicate the identify of the particular supply in the form of batch No. or lot no. and the date of receipt of the consignment.

All the raw materials shall be sampled and got tested either by the in house Ayurvedic, Siddha and Unani experts (Quality control techinical person) or by the laboratories approved by the Government and shall be used only on approval after verifying . The rejected raw material should be removed from other raw material store and should be kept in separate room. Procedure of 'First in first out' should be adopted for raw materials wherever necessary. Records of the receipt, testing and approval or rejection and use of raw material shall be maintained.

1.1 (F) (B) Packaging Materials :

All packaging materials such as bottle, jars, capsules etc. shall be stored properly. All containers and closure shall be adequatley cleaned and dried before packing the products.

1.1 (F) (C) Finished Goods Stores :

The finished goods transferred from the production area after proper packaging shall be stored in the finished goods stores within an area marked "Quarantine". After the quality control laboratory and the experts have checked the correctness of finished goods with reference to its packing/labeling as well as the finished product quality as prescribed , then it will be moved to "Approved Finished Goods Stock" area. Only approved finished goods shall be dispatched as per marketing requirements. Distribution records shall be maintained as required.

If any Ayurvedic, Siddha and Unani drug needs special storage conditions, finished goods store shall provide necessary enviornmental requirements.

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1.1 (G) Working space :

The manufacturing area shall provide adequate space (manufacture and quality control) for orderly placement of equipment and material used in any of the operations for which these are employed so as to facilitate easy and safe working and to minimize or to eliminate any risk of mix-up between different drugs, raw materials and to prevent the possibility of cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises.

1.1 (H) Health Clothing, Sanitation and Hygiene of Workers :

All workers employed in the Factory shall be free from contagious diseases. The clothing of the workers shall consist of proper uniform suitable to the nature of work and the climate and shall be clean. The uniform shall also include cloth or synthetic covering for hands, feet and head wherever required. Adequate facilities for personal cleanliness such as clean towels, soap and scrubbing brushes shall be provided. Separate provision shall be made for labatories to be used by men and women, and such labatories shall be located at places separated from the processing rooms. Workers will also be provided facilities for changing their clothers and to keep their personal belongings.

B. LIST OF MACHINERY, EQUIPMENT AND MINIMUM MANUFACTURING PERMISES REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF UNANI SYSTEM OF MEDICINES.

Sl.No.	Category of Medicine	Minimum manufacturing Space required	Machinery/ equipment recommended
(1)	(2)	(3)	(4)
1.		1200 square feet covered area with separate cabins, Partitions for each Activity. If Ayurveda/ Siddha, Medicines are also manufactured in same premises an additional areas of 400 square feet will be required.	

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1.	Itrifal Tiryao/ majoon/Laooq JawarishKhamiras	100 Sq. feet	Grinder Pulveriser Sieves, powder mixer (if required) S.S. Patilas, Bhatti and other accessories, Planter mixer for Khamiras.
14.	Tail/Ghrit Ney	100 Sq. feet	Bhatti, Kadahi/S.S. Patila S.S. Storage Containers, Filtration equipment, filling tank with tap/ Liquid filling machine.
16.	Aschyotan/ Netra Malham Panir	100 Sq. feet	Hot air oven electrically heated with thermostatic control, cettle gas or electrically heated with suitable mixing arrangements collation mill or ointment mill, tube filling equipment, mixing and storage tanks of staninless steel or of other sutiable material sintered glass funnel, seitz filter or filter candle, liquid filling equipment, autoclavee.
16.	Each manufacturing unit will have a separate area for Bhatti, furnaces, boilers, puta, etc. This will have proper ventilation, removal of smoke, prevention of flies, insects, dust etc. The furnace section could have tin roof.	200 Sq. feet	

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1.1 (I) Medical Services :

The Manufacturer shall also provide:—

(c) adequate facilities for first aid ;

(d) medical examination of workers at the time of employment and periodcial check up thereafter by a physician once a year, with particular attention being devoted to freedom from infections. Records thereof shall be maintained.

1.1 (J) Equipments :

For carrying out manufacturing depending on the size of operation and the nature of product manufactured, suitable equipment either manually operated or operated semi-automatically (Electrical or steam based) or fully automatic machinery shall be made available. These may include machines for use in the process of manufacture such as crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying filling, labelling and packing etc. To ensure ease in movement of workers and oderlines in operations a suitably adequate space will be ensured between two machines or rows of machines. These Equipments have to be properly installed and maintained with proper cleaning.

Proper standard operational procedures (SOPs) for cleaning, maintaining & performance of every machine should be laid down.

1.1 (K) Batch Manufacturing Records :

The licencee shall maintain batch manufacturing record of each batch of Ayurvedic, Siddha and Unani drugs manufactured irrespective of the type of product manufactured (classical preparation or patient and proprietary medicines). Manufacturing reocrds are required to provide an account of the list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurveda, Siddha and Unani mentioned in the First Schedule of the Drugs and Cosmetic Act, 1940 (23 of 1940). These tests may include any in-house or pharmacopoeial test adopted by

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the manufacturer in the raw material or in the process material and in the finished product. These records shall be duly signed by Production and Quality Control Personnel respectively. Details of transfer of manufactured drug to the finished products store including dates and quantity of drugs transferred along with record of testing of the finished product, if any, and packaging, records shall be maintained . Only after the manufactured drugs have been verified and accepted quality shall be allowed to be cleared for sale.

It should be essential to maintain the record of date, manpower, machine and equipments used and to keep in process record of various shodhana, Bhavana, burning in fire and specific grindings in terms of internal use.

1.1 (L) Distribution Records :

Records of sale and distribution of each batch of Ayurveda, Siddha and Unani Drugs shall be maintained in order to facilitate prompt and complete recall of the batch, if necessary.

1.1 (M) Record of Market Complaints :

Manufacturers shall maintian a register to record all reports of market complaints received regarding the products sold in the market. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufactures regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing authority . The Register shall also be available for inspection during any inspection of the premises.

Reports of any adverse reaction resulting from the use of Ayurveda, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

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1.1 (N) Quality Control :

Every licensee is required to provide facility for quality control section in his own premises or through Government approved testing laboratory. The test shall be as per the Ayurveda, Siddha and Unani pharmacopoeial standard . Where the tests are not available, the test should be performed according to the manufactures specification or other information availble. The quality control section shall verify all the raw materials, monitor in process, quality checks and control the quality of finished product being released to finished goods store/ ware house. Preferably for such Quality control there will be a separate expert. The quality control section shall have the following faiclities:

1. There should be 150 sq. feet area for quality control section.
2. For identification of raw drugs, reference books and reference samples should be maintained.
3. Manufacturing record should be maintained for the various processes.
4. To verify the finished products, controlled samples of finished products of each batch will be kept for 3 years.
5. To supervise and monitor adequacy of conditions under which raw mateirals, semi-finished products and finished products are stored.
6. Keep record in establishing shelf life and storage requirements for the drugs.
7. Manufactures who are manufacturing patent proprietory Ayurveda, Siddha and Unani medicines shall provide their own specification and control references in respect of such formulated drugs.
8. The record of specific method and procedure of preparation, that is, "Bhavana", "Mardana" and "Puta" and the record of every process carried out by the manufacturer shall be maintained.

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(1)	(2)	(3)	(4)
8.	Ointment/ Marhameasi	100 Sq. feet	Tube filling machine, Crimping Medicine/ Ointment Mixer, End Runner /Mill (Where required), S.S. Storage Container S.S. Patila.
10.	Pak/Avaleh/ Khand/Modak/ Lakayam	100 Sq. feet	Bhatti section fitted with Exhaust fan and should be fly proof, Iron Kadani/S.S. Patila and S.S. Storage container.
10.	Panak Syrup/ Peavahi Kwath Manapaku	150 Sq. feet	Tinctum press, exhaust fan fitted and fly proof, Bhatti section, Bottle washing Machine, filter press/Grafilter Liquid filling tan with tap/ liquid filling machine , P.P. Copping Machine.
11.	Asava/Aristha	200 Sq. feet	Same as mentioned above. Fermentation tanks containers and Distillation Plant where necessary, Filter Press.
12.	Sura	100 Sq. feet	Same as mentioned above. plus Distillation plant and Transfer pump.
13.	Ark Tinir	100 Sq. feet	Maceration tank, Distillation plant, Liquid/ fitting tank with tap Gravity filter/ Filter press, Visual inspection box.

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For the manufacturing of Ayurveda, Siddha and Unani drug that can be sterilised in their final containers, the design of the areas shall preclude the possibility of the products intended for sterilisation being mixed with or taken to be products already sterilised. In case of terminally sterilised products, the design of the areas shall preclude the possibility of mix up between non-sterile and sterile products.

(B) **Precautions against contamination and mix**

(a) Carrying out manufacturing operations in a separate block of adequately isolated building or operating in an isolated encosure within the building.

(b) Using appropriate pressure differential in the process area.

(c) Providing a suitable exhaust system.

(d) Designing laminar flow sterile air systems for sterile products.

(e) The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity.

(f) Individual containers of liquids, and opthalmic solutions shall be examined aganist balck-white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matter.

(g) Expert technical staff approved by the Licensing Authority shall check and compare actual yield against theoretical yield before final distribution of the batch.

All process controls as required under master formula including room temperature relative humidity, volume filled, leakage and clarity shall be checked and recorded.

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PART- II

A. LIST OF MACHINERY, EQUIPMENT AND MINIMUM MANUFACTURING PERMISES REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF AYURVEDIC SIDDHA SYSTEM OF MEDICINES.

Sl.No.	Category of Medicine	Minimum manufacturing Space required	Machinery/ equipment recommended
(1)	(2)	(3)	(4)
		1200 saquare feet covered area with separate cabins, Partitions for each Activity. If Unani Medicines are manufactured in same premises an additional Area of 400 square feet will be required.	
1.	Anjana/Pisti	100 Sq. feet	Karel/mechanised/motorised, kharel, End runner/Ball-Mill Sieves/Shifter
2.	Churna/Nasya Manjan/Lepa Kwath Churn	200 Sq. feet	Grinder/Disintegrator/ Pulverisar/Powder mixer/ sieves/shifter
3.	Pills/Vatti/Gutika Matirai	100 Sq. feet	Ball Mill, Massmixer powder mixer pill/Vati cutting machine, stainless steel trays Containers for Storage. Driers/Mechanised chattee (for mixing guggul) where required.
4.	Tablets	100 Sq.feet	Ball Mill, Mass Mixer/ Powdermixer Granulator drier, Tablet compressing Machine and sugarcoating Poliching pak in case of sugar coated tablets, mechanised chattee (for mixing of guggul) where required.

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(1)	(2)	(3)	(4)
5.	Kupi pakva/ Ksara/Parpati/ Lavana Bhasma Satva/Sindura Karpu/Uppu/Param	150 Sq. feet	Bhatti, Karahi/ Stainless Steel Vessels/Patila Flask, Multani Matti/Plaster of Paris,Copper Rod, Earthen container, Gaj Put Bhatti, Muffle furnace (Electrically operated) End/Edge Runner, Exhaust Fan, Wooden/S.S. Spatula.
6.	Kajal	100 Sq. feet	Earthen lamps for Collection of Kajal, Tipple Roller Mill, End Runner, Sieves, S.S. Patila, Filling/packing and manufacturing room should be provided with exhaust fan & ultra violet lamps
7.	Capsules	100 Sq. feet	Air Conditioner, De humidi fier, hygrometer, Thermo-meter, Capsule filling Machine and chemical balance.

9. The standards for identity, purity and strength as given in respective pharmacopoeias of Ayurveda, Siddha and Unani systems of medicines published by Government of India shall be complied with.

10. All raw materials will be monitored for fungal, bacterial contamination with a vew to minimise such contamination.

11. Quality control section will have a minimum of

a. one person with Degree qualifcation in Ayurveda/Siddha/ Unani (A.S.U) as per Schedule II of Indian Medicine Centeral Council Act, 1970 (84 of 1970) of a recognized university or Board.

b. Provided that Bachelor of Pharmacy, Pharmacognosy and Chemistry be associated with the quality control section.

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3.0 Requirement for Sterile Product :

(A) Manufacturing Areas

For the manufacture of sterile Ayurveda, Unani and Siddha drugs, separate enclosed areas specifically designed for the purpose shall be provided. These areas shall be provided with air locks for entry and shall be essential dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply shall be filtered through bacteria retaining filters (HEPA Filters) and shall be at a pressure higher than in the adjacent areas. The filters shall be checked for performance on installation and periodically thereafter the record of checks shall be maintained. All the surfaces in sterile manufacturing areas shall be designed to facilitate cleaning and disinfection. For sterile manufacturing routine microbial counts of all Ayurveda, Siddha and Unani drug manufacturing areas shall be carried out during operations. Results of such count shall be checked aganist established in-house standards and record maintained. Access to manufactuirng areas shall be resticted to minimum number of authorised personnel. Special procedure to be followed for entering and leaving the manufacturing areas shall be written down and displayed.

(1)	(2)	(3)	(4)
2.	Arq.	100 Sq. feet	Distillation Plant (garembic) S.S. storage Tank, Boiling Vessel, Gravity filter ,Bottle Filling machine, Bottle washing machine, Bottle drier.
3.	Habb (Pills)	100 Sq. feet	Grinder/Pulverisar, Sieves Powder mixer,(Where required) Trays.
4.	Sufoof (Powder)	100 Sq. feet	Grinder/Pulverisar, Sieves Trays, Secops, Powder mixer, (Where required).
5.	Raughan (oils) (Crushing & Boiling)	100 Sq. feet	Oil Expellar, S.S. Patilas Oil filter Bottle, filling Machine Bottle drier, Bhatti.

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(1)	(2)	(3)	(4)
6.	Shiyaf, Surma, Kajal.	100 Sq. feet	End runner, mixing S.S. Vessel.
7.	Marham, Zimad, (Ointment)	100 Sq. feet	Kharal, Bhatti, End runner Grinder, Pulveriser, Tripple Roller Mill (if needed).
8.	Qurs (Tab)	100 Sq. feet	Grinder/Pulveriser, Sieves Powder mixer (where needed) Granulator, Drier, Tablet, Compressing Machine, Die punches Trays, O.T. Apparatus, Balance with weights, Scoops, Sugar Coating Pan, polishing pan, Heater.
9.	Kushta	100 Sq. feet	Bhatti, Kharal, Sil Batta, Eartern pots.
10.	Murabba	100 Sq. feet	Aluminimum Vessels 50-100 kgs. Capacity, Gendna, Bhatti.
11.	Capsule	100 Sq. feet	Pulveriser, Powder mixer (where needed), capsule filling machine, Air Conditioner, Dehumidifier Balance with weights, storage- containers, glass.
12.	Sharbat & Jushanda	100 Sq. feet	Tinctum Press, exhausted fan fitted, Bhatti section, Bottle Washing machine, Filter Press Gravity Filter Liquid filling tank with tap/ liquid filling Machine, PP capping machine, air oven electrically heated with Thermostatic control, cettle.

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(1)	(2)	(3)	(4)
13.	Qutoot Chasm Marham (Eye drops Eype ointment)	100 Sq. feet	Hot air oven electrically heated with Thermostatic control, Cettle.
14.	Each Manufacturing unit will have a separate area for Bhatti, furnaces, boilers, putta etc. This will have proper Ventilation, removal of smoke, prevention of flies, insects, dust etc.	200 Sq. feet	

Note:

The above requirements of machinery, equipments, space, qualifications are made subject to the modification at the discretion of the Licensing Authority; if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter then in the circumstances in a partiuclar case.

[No. K. 11020/5/97- DCC (ISM)]

L. PRASAD, Jt .Secy.

Foot - Note:

The Principle rules were published in the official Gazette vide notification No. F.28-10/45H(1) dated 21-12-1945 and last amended vide GSR 352 (E) dated 26-04-2000 . The Drugs and Cosmetics Rules, 1945 as amended up to 1-5-1979 is contained in the pubilication of the Ministry of Health and Family Welfare (Department of Health) containing the Drugs and Cosmetics Act, 1940 (PDGHS-61)

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